

337484

8EHD-11-18417

August 12, 2011

11 AUG 16 PM 7:34



Via Federal Express

Document Processing Center (7407M)
EPA East – Room 6428
(Attn: TSCA Section 8(e) Coordinator)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

**CONTAINS TSCA CONFIDENTIAL
BUSINESS INFORMATION**

Re: [REDACTED]; TSCA Section 8(e) Submission for [REDACTED]
(CASRN [REDACTED])

Dear Sir or Madam:

[REDACTED] (“[REDACTED]”) hereby submits to the U.S. Environmental Protection Agency (“EPA”) under section 8(e) of the Toxic Substances Control Act (“TSCA”) information regarding a draft report on a four-week oral toxicity study in rats using the test substance [REDACTED], which has the Chemical Abstracts Service Registry Number (“CASRN”) [REDACTED] and is not listed on the TSCA Inventory. The test substance was imported for internal company use only under TSCA R&D exemption.

[REDACTED] studied the oral toxicity of [REDACTED] when administered daily to rats over a period of four consecutive weeks. Draft data also includes observation of recovery from any potential treatment-related effects over a period of four consecutive weeks. Four groups, each of five male and five female rats, received the test item by gavage at dosages of 5, 20 and 60 mg/kg/day (for males) and 20, 60 and, in the high dose group, 200 mg/kg/day from Day 1 to Day 19 and 100 mg/kg/day from Day 20 to Day 28 (for females). The control and high dose groups consisted of additional 5 males + 5 females for the recovery period. Observations were recorded during dosing and at necropsy. See Attachment 1 for a summary of the draft report results.

If you have any questions regarding this submission, please do not hesitate to contact [REDACTED] at [REDACTED] or [REDACTED].

Sincerely,



[REDACTED], President

Enclosure – Attachment 1

cc: [REDACTED], [REDACTED]

Company Sanitized

Summary of Draft Report Results

Based on the draft study results, a no observed adverse effect level (“NOAEL”) could not be established for the substance.